PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2005/000855	07.03.2005	05.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61B19/00

Applicant
DEPUY INTERNATIONAL LTD

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2005/000855

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 33-46

because:

☒ the said international application, or the said claims Nos. 33-46 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 33-46

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5,18-32,47-49
	No:	Claims	1-4,6-17
Inventive step (IS)	Yes:	Claims	18,19,25,26
	No:	Claims	5,20-24,27-32,47-49
Industrial applicability (IA)	Yes:	Claims	1-32,47-49
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Method claims 33-46 define methods for treatment of the human or animal body by surgery practised on the human or animal body. Therefore no search has been performed for the subject matter of these claims (see Article 17 (2) PCT and Rule 39.1.(iv) PCT) and no written opinion is required for the subject-matter of these method claims (see Rule 43bis.1 and Rule 67.1 (iv) PCT).

Re Item V.

1 Reference is made to the following documents:

D1 : US 6 499 488 B1 (HUNTER MARK W ET AL) 31 December 2002 (2002-12-31)

D2 : EP 0 146 699 A (GEBRUDER SULZER AKTIENGESELLSCHAFT) 3 July 1985 (1985-07-03)

D3 : US 2004/030236 A1 (MAZZOCCHI RUDY A ET AL) 12 February 2004 (2004-02-12)

D4 : US 2003/023161 A1 (GOVARI ASSAF ET AL) 30 January 2003 (2003-01-30)

2 **INDEPENDENT CLAIM 1**

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

An implantable marker (12) *for percutaneously implanting within a bone, the implantable marker comprising:*
a housing (26) *having an inner cavity* (29), *the housing having an outer surface, the outer surface* (the lower surface) *providing a bone anchor which engages at least partially with surrounding bone when implanted in use to retain the implantable marker in the bone; and*
a marker (28) *secured within the cavity, wherein the marker is detectable by a tracking system* (cf. col.5, l.40-62, fig. 1A)

The bone anchor can be integrally formed with the housing (col.5 l.55-58) such that the lower surface "provides" a bone anchor. Furthermore the embodiment of col.6 l.11-13 describes the marker to be embedded in a hollow of the screw such that also (at least part of) the lateral surfaces of the marker show a bone anchor in form of screw threads.

2.2 Also D2 discloses all features of claim 1 because the marker 11 is detectable by a tracking system in form of an imaging system.

3 INDEPENDENT CLAIM 20

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 20 does not involve an inventive step in the sense of Article 33(3)PCT.

3.1.1 Document D3, which is considered to represent the most relevant state of the art to the subject matter of claim 20, discloses (the references in parentheses applying to this document):

> *A kit for percutaneously implanting an Implantable marker in a bone, the kit comprising: a guide instrument* (700) *having a guide channel* (702) *extending at least partially along a longitudinal axis thereof and for receiving an implantable marker therein;*
> *an insertion tool* (606) *receivable within the channel of the guide and translatable at least partially along the longitudinal axis, the insertion tool having a distal end for releasably engaging an implantable marker; and*
> *an implantable marker* (100,300,600) *receivable within the channel, the implantable marker comprising a housing and a marker detectable by a tracking system, wherein the insertion tool is operable to drive the implantable marker into the bone* (cf. par. 44-49; fig.6-11);
>
> The marker (300) itself can be e.g. a magnetic field sensor.

3.1.2 The subject-matter of independent claim 20 differs from the disclosure of D1 in that the marker is embedded in a cavity. A marker enclosed in the cavity of an implantable marker however is known from D1 and D2 and the skilled person would see it as an obvious alternative to embed the marker in the retaining member. The proposed solution in independent claim 20 thus cannot be considered inventive (Article 33(3) PCT).

4 INDEPENDENT CLAIM 47

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 47 does not involve an inventive step in the sense of Article 33(3)PCT.

4.1.1 Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 47, discloses (the references in parentheses applying to this document):

> *An implantable marker* (12) *for percutaneously implanting within a bone, the implantable marker comprising:*

a housing having a body section (26,14 integrated), *a distal end* (18) *and a proximal end, wherein the body section is cylindrical and defines a cavity therein the distal end is tapered, the proximal end has a connector* (surfaces 31) *for engaging an insertion tool, and wherein the housing has an outer surface bearing a screw thread; and a marker* (28) *enclosed within the cavity, the marker being hermetically sealed and wirelessly detectable* (col.5, l.16-18) *by a tracking system using electromagnetic radiation within the radio frequency part of the electromagnetic spectrum, and wherein the implantable marker is retained in the bone in use by the interaction of the screw thread and surrounding bone*;

4.1.2 Although the embodiment of col. 6, l.10-12 presumably also discloses the following feature, in terms of express disclosure the subject-matter of independent claim 47 differs from the marker of D1 in that the marker and cavity are configured such that the marker is located within the surrounding bone when the implantable marker is implanted in the bone in use.

4.1.3 The problem to be solved by the present invention may therefore be regarded as minimizing the disturbance on the bone surface during long term implantation.

4.1.4 In view of D2 the solution proposed in claim 47 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) because the marker 11 in D2 fig. 3 is embedded in a cavity of the screw body (12), the screw thread covering the whole lateral surface of the marker body such that upon implantation the marker is located within the bone mass.

4.1.5 Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 47 thus cannot be considered inventive (Article 33(3) PCT).

5 DEPENDENT CLAIMS 2-17, 21-24, 27-32,48,49

Dependent claims 2-17, 21-24, 27-32, 48,49 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see the cited documents and passages.